

REMARKS

The above amendments to the above-captioned application along with the following remarks are being submitted as a full and complete response to the Official Action dated June 17, 2004. In view of the above amendments and the following remarks, the Examiner is respectfully requested to give due reconsideration to this application, to indicate the allowability of the claims, and to pass this case to issue.

Status of the Claims

Claims 1 and 6-14 are under consideration in this application. Claims 2-5 and 15-18 are being cancelled without prejudice or disclaimer. Claims 1 and 14 are being amended, as set forth above and in the attached marked-up presentation of the claim amendments, in order to more particularly define and distinctly claim Applicants' invention.

Additional Amendments

The claims are being amended or added to correct formal errors and/or to better disclose or describe the features of the present invention as claimed. Applicants hereby submit that no new matter is being introduced into the application through the submission of this response.

Allowed Subject Matters

Claims 3, 4, and 16-17 would be allowed if they are rewritten in independent form to include all the limitations of the base claim and any intervening claims.

Prior Art Rejection

Claims 1-2, 5-6, 8-10, 14-15 and 18 were rejected under 35 U.S.C. § 102(b) on the grounds of being anticipated by US Pat. No. 5,057,426 to Henco et al. (hereinafter "Henco"), and claims 1-2, 5-9, 11-12, 14-15 and 18 were further rejected under 35 U.S.C. § 102(e) as being anticipated by US Pat. No. 6,383,393 to Colpan et al. (hereinafter "Colpan"). Claims 1-2, 5-15 and 18 were rejected under 35 U.S.C. § 103(a) on the grounds of being unpatentable over Colpan in view of US Pat. App. Pub. No. 2001/0018219 of Igarishi et al. (hereinafter "Igarishi"). The Examiner specifically cited Sigma Catalog, page 1031 (hereinafter "Sigma") to show the chemical elements of triton. These rejections have been carefully considered, but are most respectfully traversed.

The method for isolating and purifying nucleic acids of the present invention, as now recited in claim 1, comprises: providing a mixed solution containing the nucleic acids, salts, and at least one organic solvent; adsorbing the nucleic acids on an adsorption support; washing the support adsorbed with the nucleic acids with a washing buffer; desorbing the nucleic acids from the support with an elution buffer thereby recovering the nucleic acids (page 3, lines 8-14). The organic solvent includes at least one of ethylene glycol dimethyl ether, ethylene glycol diethyl ether, propylene glycol dimethyl ether, propylene glycol diethyl ether, diethylene glycol dimethyl ether, diethylene glycol diethyl ether, tetrahydrofuran, 1,4-dioxane, propylene glycol monomethyl ether acetate, ethyl lactate, hydroxyacetone, acetone, and methyl ethyl ketone (p. 13, lines 3-17 & Table 1).

The present invention as set forth in claim 14 is directed to a reagents kit for use in isolating and purifying nucleic acids by causing the nucleic acids to be adsorbed on an adsorption support, comprising: a mixed solution containing salts and an organic solvent for enabling adsorption of nucleic acids, a washing buffer, and an elution buffer. The organic solvent comprises at least one of ethylene glycol dimethyl ether, ethylene glycol diethyl ether, propylene glycol dimethyl ether, propylene glycol diethyl ether, diethylene glycol dimethyl ether, diethylene glycol diethyl ether, tetrahydrofuran, 1,4-dioxane, propylene glycol monomethyl ether acetate, ethyl lactate, hydroxyacetone, acetone, and methyl ethyl ketone.

As defined in the Electrochemistry Dictionary which is available online at <http://electrochem.cwru.edu/ed/dict.htm#a28>, *adsorption* means adhere or attach molecules or ions to outer surfaces or interfaces so as to increase the concentration of a solute in the vicinity of a solid surface, over that in the bulk of the solution, due to the attractive interaction between the solid immersed into the solution and the solute. The binding to the surface is usually weak and reversible. It is a surface process such that the accumulating molecules do **not** actually penetrate the substance on which they are formed. The term is not to be confused with absorption (filling of pores in a solid). The invention reduces viscosity and promotes defoaming of the obtained nucleic acid-containing solution. The yield of the recovered or collected nucleic acids is increased without incurring more contamination. Additionally, the nucleic acids recovery time is shortened (p. 4, lines 17-22).

Applicants contend that none of the cited prior art references teaches or suggests such an adsorption method or reagents kit for isolating and purifying nucleic acids.

In contrast to the present invention, Henco separates long chain nucleic acids from other substances in solutions containing nucleic acids and other materials using the porous matrix modified to form an anion exchanger (col.1, lines 5-14; col.5, lines 31-40; claim 1). An organic solvent of Triton is used to extract buffer to release DNA from the phage (col.12, lines 62-68), to isolate cellular DNA from sperm (col.13, lines 16-22), and lyse CMV viruses (col.13, lines 66-col.14, line 2). Henco's organic solvent only includes Triton, rather than "at least one of ethylene glycol dimethyl ether, ethylene glycol diethyl ether, propylene glycol dimethyl ether, propylene glycol diethyl ether, diethylene glycol dimethyl ether, diethylene glycol diethyl ether, tetrahydrofuran, 1,4-dioxane, propylene glycol monomethyl ether acetate, ethyl lactate, hydroxyacetone, acetone, and methyl ethyl ketone" according to the invention.

Colpan purifies and separates nucleic acid mixtures by chromatography, using the aqueous adsorption solution with a high concentration of salts contains 1 to 50% by volume of an aliphatic alcohol with a chain length of from 1 to 5 carbon atoms or polyethylene glycol (col.1, lines 5-10; col.5, lines 3-6). In example 7, an organic solvent (phenol, chloroform, ether), and a 5-100% detergent (NP40; Tween 20, Triton X-100, SDS, CTAB) are optionally added to efficiently lyse all eukaryotic and/or prokaryotic cells and/or viruses and to denature and enzymatically degrade proteins (concomitantly removing the proteins bound to the nucleic acids) (col.9, lines 12-26). Then, 95-100% alcohol (methanol, ethanol, n-propanol, isopropanol, PEG, secondary and tertiary, short-chain or long-chain alcohols) is added to bind nucleic acids to the device (col.9, lines 26-31). First of all, Colpan's organic solvent only includes phenol, chloroform, ether, rather than "at least one of ethylene glycol dimethyl ether, ethylene glycol diethyl ether, propylene glycol dimethyl ether, propylene glycol diethyl ether, diethylene glycol dimethyl ether, diethylene glycol diethyl ether, tetrahydrofuran, 1,4-dioxane, propylene glycol monomethyl ether acetate, ethyl lactate, hydroxyacetone, acetone, and methyl ethyl ketone" according to the invention. Secondly, ether and detergent are optionally added for efficient lysis, rather than being mixed with the nucleic acids and salts to promote the adsorption of the nucleic onto an adsorption support according to the invention. In other words, Colpan's use of ether and the intended purpose of using ether are essentially different from the use and purpose of the organic solvent according to the invention.

Igarashi was relied upon by the Examiner to teach "repeating absorption, binding, and washing on identical stationary phase and finally eluting nucleic acid (p. 7, 7th paragraph of the outstanding office action)." Igarashi merely provides specimens in contact with a stationary phase

to extract nucleic acids, to capture nucleic acids from the specimens by a single stationary phase, and to extract thereof by an elute ([0022]). NaCl is used as a substance to accelerate nucleic components to be bound with the stationary phase ([0083]). However, Igarashi fails to compensate for the deficiencies of Henco and Colpan as discussed above.

Accordingly, the present invention as now recited in the independent claims 1 and 14 is distinguishable and thereby allowable over the rejections raised in the Office Action. The withdrawal of the outstanding prior art rejections is in order, and is respectfully solicited.

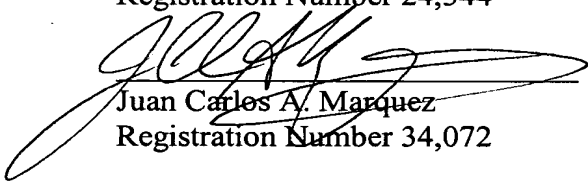
Conclusion

In view of all the above, Applicants respectfully submit that certain clear and distinct differences as discussed exist between the present invention as now claimed and the prior art references upon which the rejections in the Office Action rely. These differences are more than sufficient that the present invention as now claimed would not have been anticipated nor rendered obvious given the prior art. Rather, the present invention as a whole is distinguishable, and thereby allowable over the prior art.

Favorable reconsideration of this application as amended is respectfully solicited. Should there be any outstanding issues requiring discussion that would further the prosecution and allowance of the above-captioned application, the Examiner is invited to contact the Applicants' undersigned representative at the address and phone number indicated below.

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